Remarks made by Dr. Adrian Kantrowitz in testimony before the United States Senate Committee on Government Operations, Subcommittee on Government Research, Senator Fred R. Harris, Chairman, March 16, 1967.

It is indeed gratifying that this distinguished committee has raised questions relating to the adequacy of federal institutions for biomedical development. In the area of applying engineering technology in medicine, it is an especially timely and important examination. Here we have the exciting prospect of watching a new, hybrid field of science come into being and a challenging opportunity to guide it so that its enormous potential will be realized for the betterment and prolongation of human life.

In speaking to you today I draw upon my experience as a practicing cardiovascular surgeon and investigator. I would like to remark upon the functioning of federal agencies as they have affected my work: this is the only real area of my competence. I have taken the liberty of writing to a few of my colleagues in artificial organ research regarding the questions posed by this Subcommittee and have with me their replies which I will incorporate into my remarks. It is my hope that some thoughts drawn from our associations in the engineering technologies will bear on the questions of concern to this Subcommittee.

It is universally recognized that the United States has earned preeminence in the world today in most areas of medical research and care. In my own field of cardiac surgery, although significant contributions have come from investigators in other countries, pump oxygenators and the techniques for surgery on the open heart are the accomplishments of American pioneers like Dr. John Gibbon Jr., Dr. Clarence Dennis, and Dr. Walton Lillehei. In the decades since World War II, it is to the United States that young physicians have come for periods of training and research.

This international leadership is directly related to the funds allocated by Congress to the National Institutes of Health. In the overall, these resources and their attendant power have been used judiciously and with the highest integrity. The Institutes have shown remarkable discernment in recognizing problem areas, in giving the investigator with far-out ideas the opportunity to test them, in permitting investigators flexibility in research, in its concern for patient welfare. In my experience, its professional staff has been sensitive, nonbureaucratic, and unfailingly helpful in their advice on how best to use

the machinery of the Institutes for the advancement of research goals. Where new needs are emerging, the NIH should be strengthened and extended to meet them. But it is to be hoped that the record of accomplishment will be borne in mind: in the NIH we have a federal institution whose structure and policies have enabled it to fulfill its role in helping create the conditions for medical advances.

In evaluating the establishment of grant priorities, I must look to the past accomplishment of the NIH. The use of peer judgments to evaluate researchers' plans and proposals seems to me the very core of its strength. Dr. Bert Kusserow writes that "..it is not entirely clear precisely how research priorities are established at the federal level. For example, I do not know where, by whom and by what mechanism the very early and crucial policy decisions were made which ultimately resulted in the establishment of the Artificial Heart Program. Nevertheless, it is my feeling that the value judgments and other assessments necessary for the establishment of research priorities should be heavily influenced by the thinking of leading investigators in the field.

In this regard the history of science has repeatedly shown the danger of permitting research to fall to the market place or the political arena."

Institutional grants can facilitate an investigator's obtaining relatively small amounts needed for preliminary testing of new ideas. The availability of such funds for seed money has many advantages. I too am not familiar with the inner mechanisms of the NIH system of priorities but I would hope that it will provide funds for favorable consideration of grant applications from the young, little-published investigator with a fresh insight or an unorthodox approach who may be unappreciated within his own institution.

The problems of communication between engineer and physician are summarized by Dr. Galletti. "I find the primary emphasis on the engineering aspects of the (artificial heart) problem somewhat naive. Reviewing proposals for contracts certainly reveals a scarcity of original ideas. What strikes me on the medical side is the shortage of personnel with background, competence and inclination toward this aspect of applied biophysics. On the engineering side, interest is present, but the

complexity of physiologic, surgical and human aspects of the problem is often ignored to such an extent that one really wonders what kind of fruitful collaboration may be obtained by some industry-university partnerships."

The several methods currently used by the NIH and other federal agencies for communication with the scientific group are effective in a limited way. Their letters, brochures and descriptive literature are informative and appraise grantees or prospective grantees of important developments. A beneficial addition would be more frequent symposia and the publication and dissemination of their results. As Dr. Galletti points out, up to now this has been principally the responsibility of private organizations such as the American Society for Artificial Internal Organs and subgroups in various fields. Symposia, particularly in limited fields rather than large, general meetings, have been enormously valuable in the past and I personally would like to see as many as two a year.

On methods and means of increasing communication between physicians and engineers, Dr. Lillehei is of the opinion that "It might be well to consider a National Conference on this subject again inviting all of those

interested including physicians, engineers, and basic scientists. It has been approximately three years, I believe, since the last one and much new information has been developed. The success of this type of conference in regard to extracorporeal circulation and development of artificial heart valves is well known."

Though I can well understand the need to keep a tight rein on funds designated for travel, I think that this is one area where a relaxation of policy would result in a valuable and lively exchange of ideas. Dr. Kolff feels that, "Communication could be more effectively obtained if special funds were made available for holders of grants and their collaborators to travel."

Dr. Kusserow writes that, "It seems that a good beginning has been made by increased participation by engineers and others from the exact sciences in conferences and meetings of a biological or medical nature. Coupled with this is the trend on the part of the individuals of both groups to avail themselves of appropriate course work. A solid educational base in the form of sound academic biomedical training programs across the country should minimize this problem for future biomedical investigators."

Almost without exception, the educational factor was mentioned by each of my colleagues. I believe that long-range planning for adequate communications must center around government support to training programs and fellowships for both engineers and doctors. The inception of biomedical-engineering internships within the framework of present institutions might be helpful. Dr. Kusserow further adds, "Differences on background knowledge and training between medical and nonmedical members of the biomedical community can best be resolved at the training stage. The on-the-job training techniques can hardly be envisioned as a definitive solution for succeeding generations of biomedical scientists."

Dr. DeBakey has written me, "Our own experience with the artificial heart program in collaboration with the Rice University Engineering School has clearly demonstrated the great value of this type of multidisciplinary program and the need for a Bioengineering Institute. In this connection, the NIH established an agency for the development of Biomedical Engineering, and I would hope that this would be strongly supported."

I do feel that the type of bioengineering institutes proposed by Dr. DeBakey can provide the type of professional training for bioengineers of the next generation. I would foresee one or more centers with the full array of medical and engineering specialties working side by side. Besides serving as a training center, such an institute would carry on a high level or interdisciplinary research. The Soviet Union's Institute for Development of Surgical Instruments is a limited type of such a center.

Most investigators in the field would share Dr. Galletti's appraisal, "Since the Artificial Heart Program is sometimes compared to the space program, I may hazard the opinion that there is no large untapped reservior of competence with respect to the bioengineering of artificial organs and that overly ambitious programs may shrivel unless an effort is made to prepare competent new investigators."

My colleagues and I have varying opinions on the need for new federal institutions. Dr. Galletti feels that "It may sound trivial to state that medicine in the

last third of this century will no longer be dominated by the practice of surgery and drug administration, but will consider an extensive use of extracorporeal or implantable organs. That existing federal agencies are not fully prepared for this evolution is demonstrated by the fact that presently responsibilities and leadership in the field of artificial organs are scattered among various divisions of the National Institutes of Health, the Federal Drug Administration, and the National Bureau of Standards. The dispersion of initiative and responsibility both in government and private agencies makes it difficult to express valid national goals and even research priorities and long term plans." My own feeling is that new federal institutions are not only not needed, but might prove harmful. I share Dr. Kusserow's view, "The field is very young and sometime should be allowed for the evolvement, recognition, and definition of trends, aims and problems before any regulatory or controlling mechanism is established. The current federal supporting and funding structure seems to be a reasonable satisfactory mechanismfor the time being."

As I am sure is already being done, the decision making and advisory bodies of the NIH should be broadened to include members of the engineering profession and the physical and chemical sciences in their leadership.

The one federal agency which I and others would like to see created is a National Academy of Medicine which, to quote Dr. Wesolowski, "Would be associated with the National Academy of Engineers and which could be used by Congress and other governmental bodies in exactly the same fashion as the National Research Council is presently being used."

As to existing techniques for implementing plans, in Biomedical Engineering, we are considering a field in transition. Until recently, the traditional role of electronics in medicine has been limited to instrumentation... recording and monitoring. Only in the past few years has this technology been turned to the treatment of disease and the alleviation of its ravages. Advances in miniaturization and reliability coupled with the development of new materials has made it possible to consider implanted, long-lasting devices such as a cardiac pacemaker for patients with heart block, a bladder stimulator for paraplegics

with neurogenic bladder and pumps for patients in intractable left ventricular failure.

We can only guess at the number of possible applications untapped because the physician is unaware of the technological development, because the engineer is unaware of the medical need, or, when both are recognized, the means for effecting the collaboration are lacking.

As we plan for a future in which medicine and engineering are successfully cross-fertilized, we must not overlook some of the built-in difficulties. While certain pressures exist for the investigator in an academic institution--whether in medicine or engineering--there is identity between the goals of his research and the goals of his institution. For the engineer in industry interested in working on biomedical problems, unhappily this is not often true. There are, of course, a few industrial laboratories where he may be given a free hand, but more usually as soon as a problem makes important demands, understandable pressures are felt. Faced with the uncertainty of ultimately developing a marketable product, corporate management must be inhibited about investment of company resources.

There are certainly numerous instances of successful collaboration between industry and medical investigators in recent years. Several types of cardiac pacemakers in widespread clinical use evolved from engineer-physician collaboration. But a pacemaker is a relatively simple development; the medical problems were frank and well defined...and the electronics and materials solutions within the state of the art. Where more complex answers have been sought, it has proven difficult to develop stable, productive relationships. The extensive funding, the investment of time and personnel, problems of communication have militated against the large scale joining of American industry in biomedical efforts.

Subsidized and directed research and development such as the NIH Artificial Heart Program holds promise of alleviating insecure and erratic liaisons between the specialties and bringing the great talents in American industry to bear in the development of mechanical methods of assistance to the failing heart. Dr. Lillehei feels that "these objectives can undoubtedly be achieved much sooner through participation of the government, and specifically NIH, in support of the necessary research." This

utilization of our talent resources from industry has been much needed in those areas where basic physiologic problems have been resolved and solutions lie within the state of the art.

Dr. Frank Hastings and his associates are doing an excellent job in bringing the talents of industry into this area. But it is to be expected that problems will be encountered in the implementation of such a program. The importance of close interchange between the engineering group and the medical research team has been recognized, but the question of leadership is unresolved. In current requests for proposals there is commendable reference to scientific advisory and review boards and of primary monitoring of the scientific aspects of communication at the scientist to scientist level. First technologic support-type contracts required that the proposal include a statement from the medical investigator that he and the prospective contractor could work amicably. My own situation in collaborating with AVCO is unique in the unusual rapport between my brother and myself. However, in the more usual relationship, I believe the lack of clear

directive that the medical investigator's judgment should prevail when there is a difference of opinion presents a potential hazard to the realization of goals.

Testing-type contracts must ensure that the system being tested is given an objective, fair trial, i.e., that the method being tested is precisely that of the developer and that he should be satisfied that this is so. In any method there will be modifications and improvements, but these should be supported by other grants or research and development contracts.

We must guard against any tendency among engineering firms to put aside medical leadership when they have acquired a position of control after financial support has been gained through NIH grants or contracts.

The New York Times of October, 1965, headlined the spawning of a 350 million dollar industry by the marriage of medicine and electronics, which points up the contract program's likelihood of launching profitable business for many companies. The medical investigator and the NIH need some assurance that as it grows, the final voice on behalf of patient well-being is that of the physician.

In this view, I am joined by Dr. John Gibbon who wrote me "It is, of course, absurd to award a contract to industry for technological backup to a particular medical investigator and then to have the company directly responsible to the National Institutes of Health rather than to the collaborating investigator. In the many years that I worked with IBM engineers in developing several different types of heart-lung machines, I worked intimately, of course, with the engineers. They made suggestions to me concerning the type of physiologic research we should be carrying on, and we similarly made requests and suggestions to them concerning the apparatus that they were constructing for us. I cannot imagine any more satisfactory arrangement than this close collaboration. To introduce a third party into the picture to whom the industrial company is responsible, seems to me a great mistake."

It is not my suggestion that financial and administrative monitoring be placed in the hands of the medical man or his institution. On the contrary, as Dr. Kolff has said, trustees of universities and hospitals tend to be unwilling to undertake the responsibilities

involved in such grants. This must remain in NIH hands.

Working in isolation or without constant refreshment of medically oriented direction, the engineer may expend time and effort and financial support with only naive concepts of the medical realities. It would be a grievous error to reduce the role of medical scientists from positions of guidance and control in any government sponsored distribution of funds in which the ultimate application affects human life.

In summary, I feel that any work in support of a medical investigator must be under his leadership. Such assurance should form an integral part of the philosophy of the contract program.

The National Institutes of Health system of reviewing proposals by a body of one's peers has proved to be effective and reasonably free from individual prejudice. I would not like to see any inhibition of this system, but feel rather, that it should be enhanced. I would also feel that, other than the creation of a National Academy of Medical Science, it would be unwise to hastily create any new agencies in the leadership of biomedical research.

The accompanying letters are from the following:

Michael E. De Bakey, M.D.
Professor and Chairman
Cora and Webb Mading Department of Surgery
Baylor University College of Medicine
Houston, Texas

Pierre M. Galletti, M.D., Ph.D.
Professor of Physiology
Emory University
Atlanta, Georgia

John H. Gibbon, Jr., M.D.
Samuel D. Gross Professor of Surgery
and Head of the Department
The Jefferson Medical College of Philadelphia
Philadelphia, Pennsylvania

Willem J. Kolff, M.D.
Department of Artificial Organs
Cleveland Clinic
Cleveland, Ohio

Bert K. Kusserow, M.D.
(Immediate Past President, American Society for
Artificial Internal Organs)
Associate Professor of Pathology
The University of Vermont
Burlington, Vermont

C. Walton Lillehei, M.D.
Professor of Surgery
University of Minnesota
Minneapolis, Minnesota

Frank Spencer, M.D.
Professor of Surgery and Director
Department of Surgery
New York University Medical Center
New York, New York

Sigmund A. Wesolowski, M.D.
(President, American Society for Artificial
Internal Organs)
Mercy Hospital
Rockville Center, New York

Baylor University College of Medicine
Texas Medical Center | Cora and Webb Mading
Houston, Texas 77025 | Department of Surgery

March 4, 1967

Adrian Kantrowitz, M. D.
4802 Tenth Avenue
Brooklyn, New York 11219

Dear Adrian:

As I indicated to you in our recent telephone conversation, I was delighted to learn that you are going to testify before the Senate Subcommittee on Government Research regarding the adequacy of federal institutions for biomedical development.

I certainly agree with you that there is an urgent need to provide more intensive support in this field of endeavor. You will recall that the President's Commission on Heart Disease, Cancer and Stroke recommended (Recommendation No. 14) that "three Bioengineering Centers and three Rehabilitation Biomedical Engineering Research Centers be established over a five-year period in order to take advantage of the potential offered by bioengineering research in heart disease, cancer, and stroke". Our own experience with the artificial heart program in collaboration with the Rice University Engineering School has clearly demonstrated the great value of this type of multidisciplinary program and the need for a Bioengineering Institute. In this connection, the National Institutes of Health established an agency for the development of Biomedical Engineering, and I would hope that this would be strongly supported.

My best wishes.

Sincerely,

Michael E. De Bakey, M. D.

MED:bwa

EMORY UNIVERSITY
ATLANTA, GEORGIA 30322

DIVISION OF BASIC HEALTH SCIENCES

DEPARTMENT OF PHYSIOLOGY

February 27, 1967

Dr. Adrian Kantrowitz
Director of Surgical Services
Maimonides Hospital of Brooklyn
4802 Tenth Avenue
Brooklyn, N.Y. 11219

Dear Adrian:

I consider it good news that you have been invited by the Senate Subcommittee on Government Research of the Committee on Government Operations to testify regarding the adequacy of federal institutions for biomedical developments. My comments will be restricted to the domain of biomedical engineering and more specifically to that of artificial organs, since in recent years federal agencies have played an increasingly important role in supporting development and clinical trials in this field.

It may sound trivial to state that medicine in the last third of this century will no longer be dominated by the practice of surgery and drug administration, but will consider an extensive use of extracorporeal or implantable organs. That existing federal agencies are not fully prepared for this evolution is demonstrated by the fact that presently responsibilities and leadership in the field of artificial organs are scattered among various divisions of the National Institute of Health, the Federal Drug Administration, the National Bureau of Standard, etc. The role of providing communication has so far been assumed largely by private organizations such as the American Society for Artificial Internal Organs, and various subgroups of professional societies in the field of surgery, medicine or engineering. The dispersion of initiative and responsibility both in government and in private agencies makes it difficult to express valid national goals and even research priorities and long term plans.

Referring more specifically to the current practice of the Artificial Heart Program, I find the primary emphasis on the engineering aspects of the problem somewhat naive. Reviewing proposals for contracts certainly reveals a scarcity of original ideas. What strikes me on the medical side is the shortage of personnel with background, competence and inclination towards this aspect of applied biophysics. On the engineering side, interest is present, but the complexity of the physiologic, surgical and

human aspects of the problem is often ignored to such an extent that one really wonders what kind of fruitful collaboration may be obtained by some industry-university partnerships. I ask myself whether the federal government should not step in not only to set goals, but also to implement more fruitful cross-fertilization. Among the means which federal agencies could consider I suggest first the institution of training programs in the field of artificial organs, clearly designed to increase manpower on a nationwide basis and not only for the benefit of a particular institution or geographical area; second the creation of some formal or informal group of experts who could be assigned to collaborate with a particular contractor, when a promising lead is hampered by shortage of manpower; third the support of academic institutions broadly committed to the field of artificial organs in the best tradition of university-industry relationship. Since the artificial heart program is sometimes compared to the space program, I may in conclusion hazard the opinion that there is no large untapped reservoir of competence with respect to the bioengineering of artificial organs and that overly ambitious programs may shrivel unless an effort is made to prepare competent, new investigators.

Cordially yours,

Pierre M. Galletti, M.D., Ph.D.
Professor of Physiology

PMG:sg

THE JEFFERSON MEDICAL COLLEGE OF PHILADELPHIA
1025 WALNUT STREET

JOHN H. GIBBON, JR., M. D.
SAMUEL D. GROSS PROFESSOR OF SURGERY
AND HEAD OF THE DEPARTMENT

March 3, 1967

Dr. Adrian Kantrowitz
4802 Tenth Avenue
Brooklyn 19, New York

Dear Adrian:

I was very much interested in your letter of February 21, 1967. I am delighted that the Senate Subcommittee on Government Research of the Committee on Government operations has invited you to testify regarding the adequacy of federal institutions for biomedical development.

I am afraid that I am too far removed from the current field of medical investigation aided by engineers from American industry to answer the questions you raised in your letter, with the exception of the final one. It is, of course, absurd to award a contract to industry for technological backup to a particular medical investigator and then to have the company directly responsible to the National Institutes of Health rather than to the collaborating investigator. In the many years that I worked with IBM engineers in developing several different types of heart-lung machines, I worked intimately, of course, with the engineers. They made suggestions to me concerning the type of physiologic research we should be carrying on, and we similarly made requests and suggestions to them concerning the apparatus that they were constructing for us. I cannot imagine any more satisfactory arrangement than this close collaboration. To introduce a third party into the picture to whom the industrial company is responsible, seems to me a great mistake.

I am sorry that I cannot be more helpful to you, other than making the above comments.

Sincerely yours,

John H. Gibbon, Jr. mjp

John H. Gibbon, Jr., M. D.

JHGjr/mjp

Signed in Dr. Gibbon's absence

CLEVELAND CLINIC
2020 EAST 93RD STREET
CLEVELAND 6, OHIO

DEPARTMENT OF ARTIFICIAL ORGANS
WILLEM J. KOLFF, M.D.
SATORU NAKAMOTO, M.D.

February 28, 1967

Dr. Adrian Kantrowitz
4802 Tenth Avenue
Brooklyn, New York 11219

Dear Dr. Kantrowitz:

Thank you for your letter of February 21. I appreciate your request.

Artificial organs is strange to many members of study sections and it strikes the members who are traditional researchers and doctors in a funny way. Their natural reaction is negativistic. When the word "development" is mentioned the committee believes it is gadgeteering.

Communication could be more effectively obtained if special funds were made available for holders of grants and their collaborators to travel.

I am concerned that according to NIH rules new methods are abandoned too early. For example, application of a new artificial kidney may no longer be considered as research but is confused with patient care. Actually the question of how to apply the new kidney to patient care is research of a high order.

Regarding supervision of contracts to industry, I have found trustees of hospitals and universities unwilling to come near or even close to great financial responsibilities and I believe that the NIH should lend and supervise the contracts.

The need to quickly dispense monies when they have become available late in the fiscal year gives rise to hurried preparation of contract proposals and hurried assignment. It would be far better if these monies could be transferred into the next fiscal year without being subtracted from that year's budget.

Sincerely yours,

W. J. KOLFF, M.D.

WJK/llr

C O P Y

THE UNIVERSITY OF VERMONT

Department of Pathology

March 3, 1967

Adrian Kantrowitz, M.D.
4802 Tenth Avenue
Brooklyn 19, New York

Dear Adrian:

The questions posed in your letter of recent date are very broad ones. I am somewhat hesitant to pose as an authoritative information resource on this problem since my administrative activities in this area, other than those concerned with the A.S.A.I.O., have not been especially extensive. Nevertheless, a few comments which may be helpful are enclosed.

Questions One and Five may perhaps be handled jointly, since they deal with the question of increased federal participation in the biomedical area. Here, and at the present time, the federal government can effectively assist and further biomedical development by the continued and perhaps expanded support of biomedical training programs in educational institutions. Such serious and widespread problems as communication difficulty and differences in background knowledge and training between medical and nonmedical members of the biomedical community, can best be resolved at the training stage. While it is true that the current generation of biomedical researchers are overcoming these problems to a degree by means of on-the-job techniques, this can hardly be envisioned as a definitive solution for succeeding generations of biomedical scientists. With respect to question Five, I do not now see any particular advantage in the creation of a new federal institution to further development and application of biomedical knowledge. This may perhaps be something to consider at a later time. The field is very young and some time should be allowed for the evolvement, recognition, and definition of trends, aims and problems before any regulatory

or controlling mechanism is established. The current federal supporting and funding structure seems to be a reasonably satisfactory mechanism for the time being. I refer of course to the various grant agencies such as the N.I.H., etc.

With respect to question Four, dealing with communications, it seems that a good beginning is being made by increased participation by engineers and others from the exact sciences in conferences and meetings of a biological or medical nature, and vice versa. Coupled with this is the current trend on the part of individuals of both groups to avail themselves of appropriate course work, lectures, etc. Again, a solid educational base in the form of sound academic biomedical training programs across the nation should minimize this problem for future biomedical investigators.

Questions Two and Three are interesting ones to me in that it is not entirely clear precisely how research priorities are established at the federal level. For example, I do not yet know where, by whom and by what mechanism the very early and crucial policy decisions were made which ultimately resulted in the establishment of the Artificial Heart Program. Nevertheless, it is my feeling that the value judgments and other assessments necessary for the establishment of research priorities should be heavily influenced by the thinking of leading investigators in the field. In this regard the history of science has shown repeatedly the danger of permitting research to fall to the market place or the political arena.

The above are certainly very random comments, but perhaps they may be of some help. Best of luck at the hearings.

Sincerely,

/s/ Bert

Bert K. Kusserow, M.D.
Associate Professor of Pathology

UNIVERSITY OF Minnesota

MEDICAL SCHOOL
DEPARTMENT OF SURGERY · MINNEAPOLIS, MINNESOTA 55455

March 8, 1967

Dr. Adrian Kantrowitz
4802 Tenth Avenue
Brooklyn, New York

Dear Adrian:

I am very pleased to have the opportunity to support your testimony to the Subcommittee on Government Research of the Committee of Government operations in regard to the biomedical development with particular reference to cardiac assistance and/or replacement.

The heart is nothing more than a pump, and there is no logical reason that successful methods cannot be developed to assist the failing heart for temporary periods. This in turn would ultimately lead to complete, permanent replacement of the heart and/or lungs in those cases in which the damage is irreversible.

These objectives can undoubtedly be achieved much sooner through participation of the Government, and specifically NIH, in support of the necessary research.

I believe that the greater level of participation of the Federal Government in support of these objectives can be augmented with a consequent increase in the rapidity of progress.

I feel that the general guidelines that have been developed and followed over the past decades by the NIH are entirely adequate to deal with this program.

In regard to the question of methods and means of increasing communication between interested physicians and engineers, there is no doubt that this needs improvement. It might be well to consider a National Conference on this subject again inviting all of those interested including physicians, engineers, and basic scientists. It has been approximately three

years, I believe, since the last one and much new information has been developed. The success of this type of conference in regard to extracorporeal circulation and development of artificial heart valves is well known.

In the awarding of contracts and grants to specific individuals or groups, I do think that it is very important that one person be the designated responsible investigator. I doubt that any program can function satisfactorily and efficiently if there is not some one person ultimately responsible for making decisions that might be associated with considerable differences of opinion.

With very best regards, I remain

Most sincerely yours,

C. Walton Lillehei

C. Walton Lillehei, M. D.
Professor of Surgery

CWL/pb

NEW YORK UNIVERSITY MEDICAL CENTER
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Department of Surgery

February 27, 1967

Dr. Adrian Kantrowitz
Director of Surgical Services
Maimonides Hospital of Brooklyn
4802 Tenth Avenue
Brooklyn 19, New York

Dear Adrian:

As we agreed on the telephone today, Monday, February 27, I am writing to specify my thoughts about facilitating biomedical research.

My main conviction in this regard is that existing facilities are too restrictive to readily initiate such research. It is easy enough to obtain the funding when one has data and a specific project to support this, but the exploratory stages with an early marriage of industry and medicine is very difficult to initiate without some unrestricted monies to start. Usually, this requires a lot of ingenuity and energy on the part of the investigator to get such a study launched before enough data are available to obtain support from the National Institutes of Health under existing regulations. Such monies could be allocated much as current institutional grants are awarded for the support of cancer or cardiovascular teaching. They could simply be specificied biomedical institutional grant, and then leave the disposition of such monies to the individual institution.

I mention the specific experience of Joe Ransohoff of the Department of Neurosurgery here, whose energy and efforts has resulted in the development of a particularly useful pump for hydrocephalic children. This is magnetically powered, and represents a beautiful blending of talents from

engineering and medicine. It was striking, however, in the initiation of this project that the obtaining of financial support required a lot of help from local agencies who more or less supported the project on a basis of faith, rather than any precise scientific evaluation, and after the initial results were encouraging, funding in the amount of about $100,000 per year was readily obtained from NIH, but not before the initial studies had been done over a period of about two years.

I hope this information is of help.

Sincerely,

Frank C. Spencer, M.D.
Professor of Surgery and
Director, New York University
Department of Surgery

FCS:sjb

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E. G. H. LABORATORY
Sigmund A. Wesolowski, M.D.
Director

March 3, 1967

Adrian Kantrowitz, M.D.
Chairman of Surgery
Maimonides Hospital
Brooklyn, N. Y.

Dear Adrian:

Concerning your letter of February 21, 1967 dealing with the testimony that you will give to the Senate Subcommittee on Government Research of the Committee on Government operations I'll take a crack at the 5 questions that they will ask:

1. Is there need for additional attention by federal agencies in the field of biomedical development?

   Yes, there most certainly is; there should be some sort of federal agency which investigates and correlates the activities of the various federal agencies in this field to make sure there is no conflict of interests, usurption of prerogatives and overlap in expenditures with special reference to the relationship between the National Institutes of Health, the U.S. Bureau of Standards and the Food & Drug Administration.

2. An evaluation of existing federal procedures for the establishment of research priorities and long-range plans in field of biomedicine.

   The most basic and pressing need in the long-range plans is at the very basis of all developments, that is some procedure or agency must be developed to correlate better the functions of the various disciplines which are working on the same field, with a special reference to better working relations between physicians and engineers, and between engineers and physicians. This also bears directly on a Subcommittee of which I am chairman, to improve relations between physicians and engineers which is a Subcommittee of the U.S. National Committee for Engineering in Medicine and Biology under the auspices of the National Academy of Engineering. It would be pitifully short-term thinking for a long-range plan not to increase and improve the quantity and quality of intercourse between physicians, biologists and engineers in the general field of biomedicine.

3. Are existing techniques for implementing plans and priorities adequate? If not, what suggestions do you have for improving them?

I don't really know how to answer this question except insofar as the answers for questions 1 and 2 bear directly upon this. If any other factors are implied by this question I would need more facts to give a pertinent answer.

4. An evaluation of existing means of communications between the scientific community (research scientists, engineers, medical practitioners, and hospitals) and federal agencies concerned with biomedical research.

Once again I think the answers to questions 1 and 2 bear directly upon this as it also implies some agency or institution be formed for this purpose.

5. Are new or additional federal institutions needed to further development and applications of biomedical knowledge?

Yes. There is absolutely no question but what is necessary in this country is a National Academy of Medicine which would be associated or in partnership with the National Academy of Sciences, National Academy of Engineers and which could be used by Congress and other governmental bodies in exactly the same fashion as the National Research Council is presently being used. In addition, such an Academy could help correlate activities across the board in terms of governmental agencies, civilian experts and institutions working in the field of biomedics and could also correlate activities between physicians and engineers not only through this Academy but de facto by establishing a working relationship with the National Academy of Engineering as a sister.

Aside from the considerations of this particular Subcommittee a National Academy of Medicine is warranted on other grounds; for instance, it would appear to me to be a travesty that the medical community in the United States, having attained the highest degree of medical diagnostic and therapeutic perfection the world has seen, does indeed, have no National Academy of Medicine.

I tried to get you on the telephone but you apparently are even busier than I am although there may be some question as to what you're doing when you're busy but I realize how such things are. At any rate, more seriously, in September I have asked you if you would present at that time to the Nassau Academy of Medicine an evening's performance on the implantable mechanical heart. During the next week I will probably get a specific date and will so advise you and will discuss further details at that time.

If there is anything further that I can do with respect to the Senate Subcommittee

please do not hesitate to contact me by telephone or any other means of communication and I'll do whatever I can.

As ever,

Sigmund A. Wesolowski, M.D.

SAW:np